

REMARKS

Applicants have cancelled claims 1-14 and replaced them with new claims 15-26. The replacement claims cover the same subject matter of the cancelled claims. Specifically, Applicants have incorporated the limitations of cancelled claims 1-6 into new claim 15, and have presented new claims 16-26 in lieu of cancelled claims 7-14 to more particularly point out the subject matter they regard as their invention.

Applicants file herewith a supplemental information disclosure statement and copies of newly uncovered foreign patent documents and non-patent literature listed in a co-filed form PTO-1449.

Claims 15-26 are currently being examined. Reconsideration of the application, as amended, is respectfully requested in view of the new prior art and the remarks below.

Objection to the Specification

The Examiner noted that embedded hyperlinks were included in the Specification. See the Office Action, page 2, lines 7-8. At the Examiner's request, Applicants have replaced all embedded hyperlinks with plain texts.

The Examiner requested that trademarks be capitalized and accompanied by generic terminology. See the Office Action, page 2, lines 10-12. Applicants have made corrections accordingly.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-14 as lacking enablement. See the Office Action, page 3, lines 1-4. As claims 1-14 have been cancelled, Applicants will discuss new claims 15-26 instead.

Claim 15, from which claims 16-26 depend, covers isolated *Lactobacillus* strains ("lactobacteria") having the bacteriological characteristics listed in Table 14 of the Specification. These strains were selected according to their **high acid tolerance**, **high bile salt tolerance**, and **ability to lower serum cholesterol levels**. See Examples 2-4 of the Specification.

The Examiner alleged that "it is not clear that cell lines possessing the properties of [the six recited lactobacteria] are known and publicly available or can be reproducibly isolated from nature without undue experimentation ..." See the Office Action, page 3, lines 10-13. It is submitted that the six strains have already been deposited at the American Type Culture Collection (ATCC), an international depository recognized under the provisions of the Budapest Treaty.¹ See the Specification, page 10, lines 16-20. A copy of the deposit receipt issued by ATCC is enclosed herewith. See Exhibit A. Applicants have filed herewith a Declaration of Availability. In addition to ATCC, Applicants have also deposited the six strains at the Food Industry Research and Development Institute, Taiwan. See the Specification, page 10, lines 12-16.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiners rejected cancelled claims 1-14 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. According to the Examiner, "[i]t is unclear what is meant by an isolated strain having 'bacteriological characteristics.'" See the Office Action, page 6, lines 19-21. As mentioned above, Applicants will discuss new claims 15-26 instead, as claims 1-14 have been cancelled.

Applicants have recited in new claim 15 "bacteriological characteristics listed in Table 14" as a new limitation. Table 14 describes in detail the three bacteriological characteristics of the claimed lactobacteria, i.e., **high acid tolerance**, **high bile salt tolerance**, and **ability to lower serum cholesterol levels**. More specifically, the claimed lactobacteria decrease in number by only 3-4 log values after being cultured at pH 2 (a highly acidic environment) for 2 hours, decrease in number by only 0.5-2 log values in a medium containing 0.3% oxgall (a human bile salt equivalence) for 24 hours, and lower cholesterol levels by 93% or higher after being cultured anaerobically in a medium containing 0.3% oxgall and 12% horse serum for 24 hours. See Table 14 of the Specification. Claim 15, reciting Table 14, is therefore definite. So are claims 16-26, all of which are construed to incorporate by reference all the limitations of claim 15 to which they refer directly or indirectly.

¹ Applicants submit that other lactobacteria covered by claim 15 can be obtained by methods well known in the art.

The Examiner further rejected cancelled claim 11 as “[i]t is unclear what is meant by a ‘probiotically effective amount’ of an isolated strain.” See the Office Action, page 7, lines 3-4. Applicants have not recited the term “probiotically effective amount” in any of the replacement claims.

In view of the above remarks, Applicants respectfully submit that this rejection is not applicable to new claims 15-26.

Rejection under 35 U.S.C. § 102(b)

The Examiner asserted two grounds for novelty rejection. Applicants disagree and traverse below both grounds, respectively, as applied to replacement claims 15-26.

I

The Examiner rejected claims 1-14 as being anticipated by Bukowska et al., U.S. Patent 6,214,336 B1 (“Bukowska”). Applicants have cancelled claims 1-14 and will discuss new claims 15-26 instead.

As mentioned above, claim 15 covers lactobacteria having the three bacteriological characteristics described in Table 14, i.e., **high acid tolerance**, **high bile salt tolerance**, and **ability to lower serum cholesterol levels**. These lactobacteria can lower serum cholesterol levels by co-precipitating it with a deconjugated form of a bile salt. See the Specification, page 4, line 18 to page 5, line 13. In lactobacteria, a bile salt (high water solubility) is converted by bile salt hydase to a deconjugated bile salt (low water solubility). The water-insoluble deconjugated bile salt sediments with cholesterol to form a complex and the complex is subsequently excreted from the body, thereby lowering serum cholesterol levels. To lower serum cholesterol levels in humans, lactobacteria need to survive an environment where bile salt concentrations are high. As lactobacteria are administered orally, they also need to survive transit through the extremely acidic stomach. Thus, lactobacteria having both high acid tolerance and high bile salt tolerance are ideal candidates for use in lowering serum cholesterol levels.

The Examiner noted that “Bukowska et al. ... use of a strain of Lactobacillus for the manufacture of a medicament for the **reduction of the ... cholesterol level** in blood ...” See the Office Action, page 7, lines 24-26. Although Bukowska teaches using lactobacteria to lower

serum cholesterol levels, it does not mention a lactobacterium that also has both **high acid tolerance** and **high bile salt tolerance**, as required by claim 15. Thus, claim 15 is not anticipated by Bukowska.

Claims 16 and 23 are drawn respectively to a food product and a pharmaceutical composition, each containing a lactobacterium of claim 15. As both claims base their patentability on use of a lactobacterium of claim 15, they are also not anticipated by Bukowska. Neither are claims 17-22 and 24-26, all of which depend from either claim 16 or 23.

II

The Examiner rejected claims 1-11, 13, and 14 as being anticipated by Lessens et al., U.S. Patent 6,399,124 B1 ("Lessens").

According to the Examiner, "Lessens et al disclose that the ice cream comprises more than 10^6 cfu/g of lactic acid bacteria, it being possible for the said bacteria to be chosen from the groups of acidophilic bacteria consisting of *Lactobacillus acidophilus*, *Lactobacillus gasseri* ... among others ..." See the Office Action, page 9, lines 5-9. Again, as the rejected claims have been cancelled, Applicants will discuss new claims 15-26 instead.

Applicants would like to point out that, according to Lessens, the lactobacteria included in the ice cream serve two purposes: (i) prevent gastrointestinal disorders by excluding pathogenic microorganisms from intestinal cells, and/or (ii) strengthen immune system by increasing phagocytosis capacities of granulocytes. See Lessens, column 3, lines 1-7. Lessens teaches use of bacteria that are acidophilic, i.e., viable in an acidic environment, to serve the just-mentioned two purposes. However, it fails to teach use of acidophilic bacteria that also have **high bile salt tolerance**, as required by claim 15. Further, it does not mention using the acidophilic bacteria to **lower serum cholesterol levels**, as also required by claim 15. Thus, claim 15 is not anticipated by Lessens.

Claims 16 and 23 are also not anticipated by Lessens as they base their patentability on use of a lactobacterium of claim 15. Neither are claims 17-22 and 24-26, all of which depend from either claims 16 or 23.

III

For the reasons set forth above, Applicants submit that replacement claims 15-26 are not anticipated by either Bukowska or Lessens.

Rejection under 35 U.S.C. § 102(e)

The Examiner asserted two additional grounds for novelty rejection. Applicants again disagree and traverse below both grounds, respectively, as applied to replacement claims 15-26.

I

The Examiner rejected claims 1-12 and 14 as being anticipated by Koss et al., U.S. Patent Application Publication 2003/0147995 A1 ("Koss").

According to the Examiner, Koss teaches use of a frozen dessert containing a bacterial culture, e.g., a culture of lactobacteria, to lower serum cholesterol levels. See the Office Action, page 10, lines 7-16. Applicants will discuss replacement claims 15-26 instead.

Applicants note that the bacteria included in the Koss dessert serve the purpose of "improving the properties of the indigenous microflora," not lowering serum cholesterol levels. See Koss, paragraph 0061. Indeed, the cholesterol lowering property of the Koss dessert relies on another ingredient, i.e., phytosterols. According to Koss, phytosterols "have been useful for lowering serum cholesterol [levels] ..." See paragraph 0053. Further, Koss fails to teach bacteria having both high acid tolerance and high bile salt tolerance, as required by claim 15. Therefore, claim 15 is not anticipated by Koss.

As claims 16 and 23 base their patentability on use of a lactobacterium of claim 15, they are also not anticipated by Sobol. Neither are claims 17-22 and 24-26, all of which depend from either claim 16 or 23.

II

The Examiner rejected claims 1-14 as being anticipated by Sobol et al., U.S. Patent Application Publication 2003/0235559 A1 ("Sobol"). Again, replacement claims 15-26 will be discussed instead.

The Examiner correctly pointed out that Sobol teaches using lactobacteria, e.g., *Lactobacillus gasseri* and *Lactobacillus acidophilus*, to lower serum cholesterol levels. See the Office Action, page 11, lines 13-19. However, in Sobol, the lactobacteria disclosed do not have both high acid tolerance and high bile salt tolerance, as required by claim 15. Thus, claim 15 is not anticipated by Sobol.

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Claims 16 and 23 are also not anticipated by Sobol as they base their patentability on use of a lactobacterium of claim 15. Neither are claims 17-22 and 24-26, all of which depend directly or indirectly from claim 16 or 23.

III

For the foregoing reasons, replacement claims 15-26 are not anticipated by either Koss or Sobol. Applicants respectfully request that the Examiner allow the replacement claims.

CONCLUSION

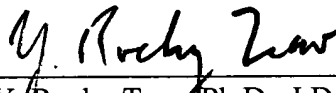
Applicants submit that replacement claims 15-26, as pending, define subject matter that is definite and novel over the prior art. Based on the remarks set forth above, Applicants submit that all claims cover allowable subject matter, and should be allowed. Early allowance by the Examiner is respectfully solicited.

Please apply any other charges to deposit account 06-1050, referencing Attorney's Docket No: 16640-002001.

Respectfully submitted,

Date: _____

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Y. Rocky Tsao, Ph.D., J.D.
Attorney for Applicant
Registration No. 34,053

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906